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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/723,374 | 11/25/2003 | Mel Kronick | 10031014-1 | 8009 |

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| EXAMINER | |
|---|---|
| CALAMITA, HEATHER | |
| **ART UNIT** | **PAPER NUMBER** |
| 1637 | |

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/723,374 | KRONICK ET AL. | |
| | Examiner | Art Unit | |
| | Heather G. Calamita, Ph.D. | 1637 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *11 and 17-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/14/2004
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicants' election of Group I, claims 1-16 in the reply filed on June 2, 2006, is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). A telephone call to Tim Joyce on August 15, 2006, was made to discuss a mistake in the restriction requirement mailed on May 17, 2006. Groups I and III should have required a species election with respect to the probes. Applicants should have been required to elect a species of probes from a) nucleic acids or b) polypeptides. After speaking with Tim Joyce a species election for the probes was made. Applicants' elected to prosecute the species of nucleic acids.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "one feature comprising a density of said probe copies that ranges from about .001 pmoles/$mm^2$ to about 10 pmoles/$mm^2$" in claims 2 and 4 and the recitation of "probe copies of said at least first population ranges from about 6 x $10^4$ probes/feature to about 6 x $10^{12}$ probes/feature" in claim 5 is unclear. It is not clear if the density of the probe feature is with respect to the probe spot on the support or if the density of the probe feature pertains to the support in its entirety.

*Claim Interpretation*

3. Claims 2, 4 and 5 recite limitations regarding probe densities it is unclear from the recitation whether the density is with respect to the probe spot on the support or if the density pertains to the support in its entirety. For the purpose of applying art, the recitation has been interpreted to mean density with respect to the probe spot on the support.

*Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16 rejected under 35 U.S.C. 102(b) as being anticipated by Albitar et al. (Molecular Diagnosis, 1997).

With regard to claim 1, Albitar et al. teach a method of producing a biopolymeric array comprising immobilizing at least a first population of a number of copies of a first probe for a first target to a surface of a solid support, wherein said number of said first population is dependant on the at least anticipated abundance of said target in a sample for which said array is designed to assay (see p.172 col. 2 under Simplified RDB Assay, where the first population of probes are the probes for codons 12, 13 and 61 and the probes are immobilized onto the membrane in 3 different concentrations 15, 75 and 375 pmol as these target is anticipated to fall within one of these concentrations).

With regard to claim 2, Albitar et al. teach at least first population is present in at least one feature comprising a density of said probe copies that ranges from about .001 pmoles/$mm^2$ to about 10 pmoles/$mm^2$ (see p.172 col. 2 under Simplified RDB Assay and Figure 1, where the probes are immobilized onto the membrane in 3 different concentrations 15, 75 and 375 pmol all

of which fall within the recited concentration range. The length of the spot is 6.35 mm and the width is 2.5 mm the density of the 15 pmol spot is 0.94 pmol, the density of the 75 pmol spot is 4.7 pmol and the density of the 375 pmol spot is 24 pmol).

With regard to claim 3, Albitar et al. teach at least first population is present in at least two replicate features (see p.173 Figure 1, where each of the probes are immobilized onto the membrane in 3 different concentrations 15, 75 and 375 pmol or 3 replicates which meets the limitation of at least 2 replicates).

With regard to claim 4, Albitar et al. teach each of said replicate features comprises a density of said probes that ranges from about .001 pmoles/$mm^2$ to about 10 pmoles/$mm^2$ (see p.172 col. 2 under Simplified RDB Assay and Figure 1, where each of the probes are immobilized onto the membrane in 3 different concentrations 15, 75 and 375 pmol all of which fall within the recited concentration range. The length of the spot is 6.35 mm and the width is 2.5 mm the density of the 15 pmol spot is 0.94 pmol, the density of the 75 pmol spot is 4.7 pmol and the density of the 375 pmol spot is 24 pmol)

With regard to claim 5, Albitar et al. teach the number of probe copies of said at least first population ranges from about $6 \times 10^4$ probes/feature to about $6 \times 10^{12}$ probes/feature (see p.172 col. 2 under Simplified RDB Assay and Figure 1, where each of the probes are immobilized onto the membrane in different concentrations (15, 75 and 375 pmol) and 15 pmol is equivalent to $9.0 \times 10^{11}$ and 75 pmol is equivalent to $4.51 \times 10^{12}$ both of which fall within the recited concentration range).

With regard to claim 6, Albitar et al. teach the number of probe copies of said at least first population is chosen so as to provide a particular signal to noise ratio for an array assay using said biopolymeric array (see p.172 col. 1 under Simplified RDB Assay, where each of the probes are immobilized onto the membrane in 3 different concentrations 15, 75 and 375 pmol these

concentrations are chosen to determine if the signal is linear i.e. optimize the signal with respect to noise).

With regard to claim 7, Albitar et al. teach performing a first assay with said sample to determine said at least anticipated abundance of said target (see p. 174 Figure 2 and p. 171 Table 1, where the assay was performed to determine the abundance of the target, i.e. its presence or absence).

With regard to claim 8, Albitar et al. teach the first assay is performed with an array (see p. 174 Figure 2 and p. 171 Table 1, where the dot blot meet the limitation of an array).

With regard to claim 9, Albitar et al. teach the array is a genome-wide array (see p. 172 col. 2 under Simplified RDB Assay 2nd full paragraph, where the DNA is extracted from peripheral blood samples, therefore the DNA hybridized is genomic DNA making the array a genome wide array).

With regard to claim 10, Albitar et al. teach the probe copies are nucleic acids (see p. 172 col. 2 under Simplified RDB Assay 1st full paragraph, where the probes are 20-base oligonucleotides).

With regard to claim 12, Albitar et al. teach the method further comprises immobilizing at least a second population of a number of copies of a second probe for a second target, wherein said number of probe copies of said second population is dependant on the at least anticipated abundance of said second target in said sample for which said array is desired to assay (see p. 173 Figures 1 and p. 174 Figure 2, where multiple populations of oligonucleotide probes are immobilized).

With regard to claim 13, Albitar et al. teach the first target is at least suspected of being present in a higher abundance than said second target in said sample and said number of probe copies of said first population is less than the number of probe copies of said second population (see Figure 1, where each of the populations of probes are immobilized onto the membrane in 3

different concentrations 15, 75 and 375 pmol where the WT is expected to be present i.e. in greater abundance than the other targets).

With regard to claim 14, Albitar et al.teach the first target is at least suspected of being present in a higher abundance than said second target in said sample and said density of said first population is less than the density of said second population (see Figure 1, where each of the populations of probes are immobilized onto the membrane in 3 different concentrations 15, 75 and 375 pmol where the WT is expected to be present i.e. in greater abundance than the other targets).

With regard to claim 15, Albitar et al. teach a method of preparing a biopolymeric array, said method comprising:

(a) determining the relative abundance of targets in a sample type for which said array is desired to be used (see p. 174 Figure 2 and p. 171 Table 1, where the assay was performed to determine the abundance of the target, i.e. its presence or absence); and

(b) immobilizing populations of different probes for respective targets at relative numbers which are dependent upon the relative abundance of said targets (see p. 174 Figure 2, p. 173 Figure 1 and p. 171 Table 1, where the populations of probes were immobilized in different concentrations and used to determine the abundance of the target, i.e. its presence or absence).

With regard to claim 16, Albitar et al. teach a method of preparing a biopolmeric array, said method comprising:

(a) determining the relative abundance of targets in a sample type for which said array is desired to be used ((see p. 174 Figure 2 and p. 171 Table 1, where the assay was performed to determine the abundance of the target, i.e. its presence or absence); and

(b) immobilizing populations of different probes for respective targets at relative total feature areas which are dependent upon the relative abundance of said targets (see p. 174 Figure 2, p. 173 Figure 1 and p. 171 Table 1, where the populations of probes were immobilized

in different concentrations and used to determine the abundance of the target, i.e. its presence or absence).

*Summary*

3. No claims were allowable.

*Correspondence*

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

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